

K003471

Safety and Effectiveness

Safety and performance of the MagnaTek ESU-400 electrosurgical generator is evaluated and verified through preclinical tests, hardware validation and software validation. Each of these areas is summarized below:

1. Preclinical Testing

Preclinical testing was performed evaluating the MagnaTek ESU-400 generator and the Valleylab Force FX as well the ERBE ICC 350 generator. Bipolar coagulation, monopolar coagulation and cut modes were used to coagulate and dissect various tissues in vitro and in vivo. The testing verified the MagnaTek ESU-400 generator performed as expected and was comparable to or better than the Valleylab Force FX or the ERBE ICC 350 generator in its ability to cut and coagulate tissue.

2. Hardware Validation

The MagnaTek ESU-400 complies with the following standards:

- FDA 510(k) Guidance for General Surgical Electrosurgical Devices
- EN 60601-1: 1990, + A1: 1993, + A2: 1995
equivalent to:
(IEC 601-1: 1988, + A1:1991, + A2:1995; Medical Electrical Equipment Part 1: General Requirements for Safety)
- EN 60601-2-2: 1994, prEN 60601-2-2: 1997, 3. edition
equivalent to:
(IEC 601-2-2: 1991, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Electrical Equipment)
- AAMI HF18: Dec. 1993, American National Standard for Electrosurgical Devices
- UL 2601-1: 1994,
equivalent to EN 60601-1
- EN 60601-1-2: Mar. 1993, Medical electrical equipment; Part 1 General requirements for safety; Collateral Standard: Electromagnetic compatibility – Requirements and tests (Emission according to Class A of EN 55011 (CISPR 11))

Validation of the MagnaTek ESU-400 generator was accomplished by a combination of analysis and testing. A Risk Analysis in accordance to DIN EN 1441 where a Failure Modes and Effects Analysis (FMEA) is a basis was also performed.

In all instances, the MagnaTek ESU-400 functioned as intended and the performance and effectiveness was as expected.

Technological Differences of the MagnaTek ESU-400 in contrast to the predicate devices are limited to:

- no simultaneous independent Coag Mode,
- one monopolar HF output in contrast to two,
- power setting by the means of potentiometers in contrast to up down keys,
- scaled Potentiometers in contrast to digital display for the power display.

Substantial Equivalence

The MagnaTek ESU-400 is substantially equivalent to other currently marketed electrosurgical generators which are referenced above. The MagnaTek ESU-400 and its predicate devices are all similar in principle of operation and technological characteristics. Thus, the MagnaTek ESU-400 raises no new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Huttinger Medizintechnik GmbH & Co.
c/o Mr. Mark Job
510(k) Third Party Program Manager
TUV Product Service, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K003471
Trade Name: MagnaTek ESU-400
Regulatory Class: II
Product Code: GEI
Dated: August 8, 2000
Received: November 8, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

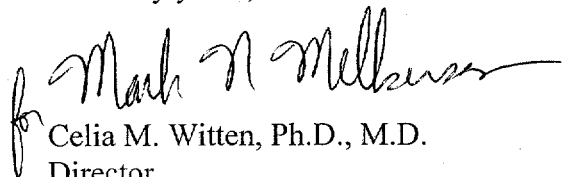
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Mark Job

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K003471

Device Name: MagnaTek ESU-400

Indications For Use:

The MagnaTek ESU-400 electrosurgical generator is designed for use in the operating room for general procedures where electrosurgical cutting and coagulation is required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N. Miller

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003471